

Abridged complaints procedure Q and A's

Please also refer to Paragraphs 6 and 9 of the PMCPA Constitution and Procedure in the 2024 Code, which comes into operation on 1 October 2024.

- 1. What is expected of the respondent company in relation to Paragraph 6.6 and the criteria: “The respondent company confirms that, as a result of its investigation, it has not identified a systemic compliance issue in relation to the matter(s) alleged.”**

When the case preparation manager writes to the respondent company under Paragraph 6.1, it will notify the company that the complaint appears to meet the criteria for the abridged complaints procedure; the case preparation manager will provide the company with an abridged complaints procedure undertaking to sign. The undertaking will contain a statement that the company confirms that its investigation has not identified a systemic compliance issue in relation to the matter(s) alleged.

To determine this, the company is expected to do a thorough and complete investigation, which will help it determine whether the issue that was the subject of the complaint was an isolated incident or an indicator of broader, widespread or recurring compliance failure (systemic compliance issue).

Example 1

For example, if the allegation was that a prescribing information (PI) link was broken on a website, it would be expected that the company would check all the PI links on the website at issue, and also check other websites which link to that same PI. If multiple broken links were found within one website and/or across multiple websites, then, as the issue was more widespread, it may be considered a systemic compliance issue. The company would then write to the case preparation manager to state that they are unable to sign the abridged complaints procedure undertaking as the company is unable to confirm that its investigation has not identified a systemic compliance issue in relation to the matter(s) alleged. The case preparation manager would then process the complaint via the full complaints procedure and may raise additional clauses when requesting a complete response to the matter of complaint from the company.

If the company can confirm that its investigation has not identified a systemic compliance issue in relation to the matter(s) alleged, there is no requirement for the company to provide the PMCPA with the details of its investigation. It only needs to complete and sign the undertaking form, including the date on which the material was last used or appeared and/or the date on which the activity last took place.

Example 2

Another example may be an allegation that an employee promoted a prescription only medicine to the public by engaging with a post on their personal social media that was originally made by an overseas affiliate and that referred to the company's medicine. In this scenario, it would be expected that the company would check if any other UK employees or UK based employees had engaged with the post in question, or with other recent similar posts.

If several employees engaged with the post in question or with recent similar posts, it may be an indicator of a more widespread issue. The company would therefore write to the case preparation manager to state that they are unable to sign the abridged complaints procedure undertaking as the company is unable to confirm that its investigation has not identified a systemic compliance issue in relation to the matter alleged. The case preparation manager would then process the complaint via the full complaints procedure and may raise additional clauses when requesting a complete response to the matter of complaint from the company.

2. What if after returning the form to say the company has not identified a systemic compliance issue, it subsequently finds one?

Once the company has signed the undertaking and provided it to the PMCPA, the case would be considered complete and the case preparation manager would draft a case report for publication summarising the allegation, acceptance of the breach by the company and that the company has provided the required undertaking and assurances (Paragraph 9.2 refers). If the company subsequently discovers that there is/was a systemic compliance issue, it can make a voluntary admission, which would be taken up as a separate case.

3. If the case preparation manager writes to the company under the full complaints procedure but on providing its response the company accepts a breach and requests that the matter be followed under the abridged complaints procedure, can the procedure path be switched?

The decision for a case to potentially be handled under the abridged complaints procedures lies with the case preparation manager. The respondent company cannot request that a complaint is taken up under the abridged complaints procedure. There may be many reasons why the case preparation manager decided to put the complaint through the full complaints procedure.

Acceptance of a breach by the company does not necessarily mean that the matter should be dealt with under the abridged procedure. For example, if the matter is subjective or may affect case precedent, the case preparation manager may want the matter to be adjudicated upon by the Panel, even if it is not a matter likely to be in breach of Clause 5.1 or Clause 2.

4. Can a complainant request in their complaint that they would like their complaint to follow either the full or abridged procedure?

The decision for a case to potentially be handled under the abridged complaints procedure lies with the case preparation manager. The complainant cannot request which complaints procedure their complaint is taken up under. The case preparation manager will determine the most appropriate route for the complaint to be assessed according to the evidence provided by the complainant and the criteria detailed in the Constitution and Procedure.

5. Can a voluntary admission go through the abridged complaints procedure?

Under the Constitution and Procedure, voluntary admissions are treated as complaints and will be assessed by the case preparation manager in the same way as a complaint from another party, to determine whether the criteria for the abridged complaints procedure is met.

6. Can intercompany-dialogue complaints go through the abridged complaints procedure?

The Constitution and Procedure does not prohibit intercompany complaints from proceeding through the abridged complaints procedure. However, in accordance with the intercompany dialogue condition as set out in Paragraph 5.11, an intercompany complaint will only be accepted if the case preparation manager is satisfied that the complainant company had informed the respondent company that that it proposed to make a formal complaint and offered intercompany dialogue at a senior level in an attempt to resolve the matter, but that this was refused or dialogue proved unsuccessful.

The PMCPA encourages alleged breaches of the Code to be resolved, wherever possible, through intercompany dialogue and for the respondent company to honour its commitment to withdraw or amend its material(s) or practice(s).

7. Can the abridged complaints procedure be used when the case preparation managers considers there is no breach of the Code?

The case preparation manager must determine whether a case should proceed through the full complaints procedure and go before the Panel, or should proceed through the abridged complaints procedure, or should not proceed at all. Rulings of no breach of the Code are made by the Panel or the Appeal Board. The case preparation manager will proceed a case (via the abridged or full complaints procedure) when it receives information from which it appears that a company **may** have contravened the Code (Paragraph 5.1). If, in the view of the case preparation manager, a complaint does not show that a company may have contravened the Code or the complainant has not provided sufficient detail to enable a company to properly respond, the case preparation manager may determine that the complaint will not proceed and the complainant will be so advised (Paragraph 5.4).